

REMARKS

Claim 78 is amended herein. Claims 42-56 and 72-81 remain pending. The allowance of claim 81 is acknowledged with gratitude.

Claim Rejections - 35 USC § 103

Applicant requests reconsideration of the rejection of claims 42-56 and 72-80 under 35 U.S.C. § 103(a) as being unpatentable over Refojo et al. (US Patent No. 4,461,303) in view of Schwebel (US Patent No. 6,641,264).

Each of the rejected independent claims 41, 72, 75 and 76 recites, in relevant part, apparatus comprising: an eye enclosure adapted to provide **an enclosed area simultaneously about (or around) both eyes** of the user **without obstructing vision through the enclosure**. Claim 78 has been amended to state this claimed feature another way. More particularly, claim 78 requires the eye enclosure to be "**free of any obstructions to vision through the enclosure**." The art of record, including particularly Refojo fails to show or suggest an eye enclosure that does not obstruct the vision through the enclosure, or which is free of any obstructions to vision through the enclosure.

The Examiner relies on Refojo as teaching an eye enclosure adapted to provide an enclosed area... without obstructing vision through the enclosure. In support of this assertion, the Examiner states, "the eye enclosure 12 [in Refojo] comprises a transparent material, as disclosed in column 5, lines 40-41, and therefore the patient is able to see through the enclosure (i.e. the enclosure does not obstruct vision)." The Examiner, however, is reading the language in the claims too narrowly. Definition 2 of Merriam-Webster's online dictionary defines the term "obstruct" as "to **hinder** from passage, action, or operation¹." Thus, a person having ordinary skill in the art would not interpret the recitation that the eye enclosure provides an enclosed area without obstructing vision as meaning that vision is not completely removed. Rather that the

¹ Merriam-Webster Online Dictionary, Definition #2 of "obstruct" (<http://www.merriam-webster.com/dictionary/obstruct>)

vision is not hindered from passing through the enclosure in any fashion. However, as pointed out by the Examiner in the previous Office action mailed June 10, 2010, Refojo discloses a series of graduations forming a scale 38 (see col. 5, ll. 4-45). The Examiner stated that the graduations "will not prevent the patient from seeing through the eye enclosure. Therefore, the eye enclosure will not obstruct the patient's vision" (see paragraph 2 on page 2 of June 10, 2010 Office action). But as explained above, obstructing vision does not require completely removing the subject's vision. Instead, any structure that hinders the vision through the enclosed area will obstruct vision through the enclosure as recited in the claims. So because Refojo discloses graduation that will, at least to some extent, hinder vision through lens 36d, Refojo does not teach an eye enclosure adapted to provide an enclosed area...**without obstructing vision through the enclosure** as recited in the claims. Applicant made a similar argument in the previous response submitted December 10, 2010 but the Examiner did not specifically address the argument in the Response to Arguments section of the current Office action. Applicant maintains that this element of the claims distinguishes the claims over the cited prior art because, the combination of Refojo and Schwebel fails to show or suggest this element of the claims.

As noted above, claim 78 requires the enclosure to be free of any obstructions to vision through the enclosure. The phrasing of claim 78 makes it even more clear that the construction of the enclosure must not in any way obstruct vision of the user.

Furthermore, as stated above, the claims also recite, "an eye enclosure adapted to provide an enclosed area **simultaneously about (or around) both eyes**." As appreciated by the Examiner, this is a distinguishing feature over the disclosure in Refojo where the chamber only provides a closed environment over a single eye. Whilst this difference may appear trivial, it is, in fact, far from trivial and clearly differentiates the present invention from the prior art. The apparatus and method of the present invention requires an enclosure which covers both eyes. The design has been carefully chosen to create an environment of sufficient volume without impairing the subject's normal activities. During testing carried out in dry conditions, subjects are often required to carry out computer tasks to mimic VDU induced dry eye symptoms.

Similarly, when the apparatus provides higher than normal activity, which is possible in the arrangements in some of the claims of the present application such as when dry eye symptoms are being relieved, it is likely to be used by the patients at their home or their place of work. In view of this, the apparatus must enable the patients to carry out normal activities. Thus the patient will need optimal vision with a clear field of view and preferably be able to wear within the eye enclosure any optical correction means that the patient may require. Thus the patient needs to be able to wear a pair of spectacles.

It is of note that the Examiner has referenced Schwebel to teach an arrangement which encloses both eyes simultaneously. It is not disputed that goggles which cover both eyes are known. What is disputed is that the skilled person to combine such an arrangement with the teaching of Refojo to arrive at the arrangement now claimed.

We would particularly point out that in Refojo, the subject is required to close their eye twice during measurements hence the subject is put in a situation during which they will not be able to carry out normal activities. Further, the shape of the enclosure disclosed in Refojo will not allow the patient to wear spectacles. The same applies with the arrangement of Schwebel. Although the embodiment illustrated in Figure 6 would enable spectacles to be worn, this is not a closed arrangement and therefore functions in a completely different way to that of Refojo and would not, even if combined with Refojo, lead the skilled man to the present invention. Indeed the skilled man is in fact taught that where glasses need to be worn, an open arrangement such as that disclosed in Figure 6 should be used.

Moreover, the arrangement in Refojo is used in a very different procedure to that of the present application. As set out in the second paragraph in column 3 of Refojo, the duration of measurement envisaged for the arrangement of Refojo is of the order of minutes. It is for this reason that the structure identified in Refojo can be used. This is in direct contrast to the arrangement of the present invention where exposure to the conditioned air is much longer, for example of the order of three hours. We appreciate that the method of use is not directly recited in the claims of the apparatus *per se*.

However, the Examiner must acknowledge that an eye enclosure that only has to be worn for a few moments is, of its very nature, completely different to one that has to be worn for some three hours and will be structured accordingly.

Also, the measurement of tear evaporation in Refojo is carried out when the air has not been applied by the inlet conduit. This is carried out while the eye is open. In this connection, the Examiner will note that there is only flow into the eye chamber of Refojo while the eye is closed in order to avoid disturbing the tear film. In contrast, the apparatus of the present invention is designed such that there can be constant airflow even when the eyes are open. The concept behind the present invention is to destabilize the tear film by exposing the eye, in one embodiment, to a more extreme dry environment, or in an alternative embodiment, to stabilize the tear film by exposing the eye to a high humidity environment. Since Schwebel does not include an air inlet it does not teach the skilled man that constant air flow could be provided.

It is noted that the system of Refojo is described as "non-intrusive" and as stated in column 4 line 50 to 56 and column 7 lines 27 to 35 of Refojo, the measurement is to be carried out at near physiologic conditions of the subject, with minimal discomfort to the subject. Thus the apparatus described in Refojo is not an apparatus which is suitable for the use to which the apparatus of the present invention is to be put which enables the eye to be exposed to conditions which are very different to normal physiologic conditions, creating symptoms of discomfort and dryness in case of a dry environment or increased ocular comfort in alleviating subjects of symptoms of dryness in the case of high humidity environments. Thus, the arrangements are different from the subject's normal conditions.

Accordingly, for the all the reasons stated above, the claims are patentable over the cited references.

Conclusion

Applicants wish to expedite prosecution of this application. If the Examiner deems the application to not be in condition for allowance, the Examiner is invited and encouraged to telephone the undersigned to discuss making an Examiner's amendment to place the application in condition for allowance.

The Commissioner is hereby authorized to charge any deficiency or overpayment of any required fee for consideration of this response to Deposit Account No. 19-1345.

Respectfully submitted,

/Kurt F. James/

Kurt F. James, Reg. No. 33,716
SENNIGER POWERS LLP
100 North Broadway, 17th Floor
St. Louis, Missouri 63102
314/345-7000

KFJ/JRJ